



MAIL STOP - PCT FFW
Docket No.: 27578U

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Inventor: ROSCHER, et al. Art Unit: XX
Appl. No.: 10/589,865 Examiner: XX
Appl. Filing Date: August 18, 2006 Confirm. No.: XX
Intl. Appl. No.: PCT/EP2005/050800
Intl. Appl. Filing Date: February 25, 2005
For: **ROFLUMILAST AND GLYCOPYRRONIUM COMBINATION**

TRANSMITTAL LETTER

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

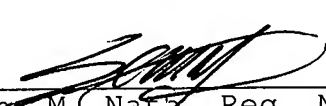
Submitted herewith for filing in the U.S. Patent and Trademark Office is the following:

1. Information Disclosure Statement; and
2. PTO Form-1449 with 43 references cited, and copies of 36 of the 43 references cited.

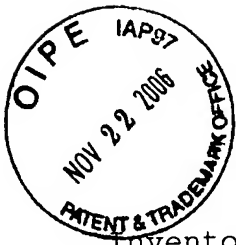
The Commissioner is hereby authorized to charge any deficiency or credit any excess to Deposit Account No. 14-0112.

Respectfully submitted,
NATH & ASSOCIATES PLLC

November 22, 2006


Gary M. Nath, Reg. No. 26,965
Sheldon M. McGee, Reg. No. 50,454
Customer No. 34375

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INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

An Information Disclosure Statement is submitted herewith pursuant to 37 C.F.R. 1.97-1.98. Please note the following particulars: [NOTE: One only of items a, b, c, and d must be checked.]

a. ☒ [XXX] The enclosed statement is being filed within three months of the filing date of a national application, or within three months of the date of entry into the national stage as set forth in 37 C.F.R. 1.491 in an international application, or before the mailing date of a first Office Action on the merits, whichever event occurs last.

b. ☐ [] The enclosed statement is being filed after a first action on the merits but before the mailing date of a final action under 37 C.F.R. 1.113, or a notice of allowance under 37 C.F.R. 1.311.

The enclosed statement is accompanied by [check one]:

☐ [] i. a certification in part (e) below as specified in 37 C.F.R. 1.97(e), or

☐ [] ii. a check in the amount required by 37 C.F.R. 1.17(p).

- c. ☐ The enclosed statement is being filed after the mailing date of a final action under 37 C.F.R. 1.113, or a notice of allowance under 37 C.F.R. 1.311, but before payment of the issue fee.
- ☐ Certification report(e) below; and
- ☐ a check in the amount as required by 1.17(p).
- d. ☐ The enclosed statement is being filed pursuant to 37 C.F.R. 1.97(i), for placement in the file.
- e. Certification [Check one] [Certification is required only if box (b)(i) or box (c) is checked.]
- ☐ I hereby certify that each item of information contained in the enclosed Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this statement,
- or
- ☐ I hereby certify that no item of information in the enclosed Information Disclosure Statement herewith was cited in a communication from a foreign patent office in a counterpart foreign application, or, to my knowledge after making reasonable inquiry, was known to any individual designated in 37 C.F.R. 1.56(c) more than three months prior to the filing of this Information Disclosure Statement.
- or
- ☐ Appropriate certification is attached.
- f. [XXX] If no check is enclosed and a fee is due in connection with this communication or if the check enclosed is insufficient, the Commissioner is authorized to charge any fee or additional fee due in connection with this communication to Deposit Account No. 14-0112.

g. [~~XX~~] Copies of the documents are attached herewith with a completed PTO Form-1449.

or

[] Copies of the documents are not attached, with a completed PTO Form-1449 as allowed under CFR 1.98(d)(1)(2). The earlier application is identified as:

and / or


[XXX] Copies of US Patents/Publications not attached, with a completed PTO Form-1449 as allowed in Official Gazette Aug. 5, 2003/ Vol. 1273, no. 1.

The Examiner is respectfully requested to cite the documents listed on the attached Form PTO-1449 in the next Office Action. In so doing, the Examiner is respectfully requested to initial in the space adjacent to the listing of each document on the Form PTO-1449, and return a copy of the initialed Form PTO-1449 with the next communication to Applicants, to confirm that these documents have been considered by the Examiner and made of record in this application.

If the Examiner has any questions or wishes to discuss this application, kindly telephone the undersigned at the below-listed number.

Respectfully submitted,
NATH & ASSOCIATES PLLC

November 22, 2006


Gary M. Nath, Reg. No. 26,965
Sheldon M. McGee, Reg. No. 50,454
Customer No. 34375

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PTO FORM-1449

**INFORMATION DISCLOSURE
CITATION**

Inventor: ROSCHER, et al.

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10/589,865Intl. Appl. No:
PCT/EP2005/050800Art Unit:
XXAppl. Filing
Date:
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February 25, 2005Examiner:
XXConfirm. No:
XX**U.S. PATENT DOCUMENTS**

Exam. Initial		Document No.	Issue/Public. Date	Inventor	Filed Date
	A1	2004/0002548	1/1/2004	Bozung et al.	6/27/2003
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	A5	6,454,193	9/24/2002	Busick et al.	4/20/2000
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	A44	Mirakhur, R.K., et al., "Glycopyrrolate: pharmacology and clinical use", <u>Anaesthesia</u> , Vol. 38, pg. 1195-1204, (1983).
	A45	Levin, R.M., et al., "Direct Measurement of the Anticholinergic Activity of a Series of Pharmacological Compounds on the Canine and Rabbit Urinary Bladder", <u>The Journal of Urology</u> , Vol. 128, pg. 396-398, (1982).
	A46	Cooke, R.D., "Glycopyrrolate in bladder dysfunction", <u>SA Medical Journal</u> , Vol. 63, pg. 3, (1983).
	A47	Demian, J., et al., "High-Performance Liquid Chromatographic Separation of 3-[(Cyclopentylhydroxyphenyl-acetyl)oxy]-1,1-Dimethyl-pyrrolidinium Bromide Diastereomers", <u>Journal of Liquid Chromatography</u> , Vol. 13, No. 4, pg. 779-787, (1990).
Examiner		Date Considered
Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP'609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.		